PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 3342078.0011	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/CA 03/01359	International filing date *(day/month/year)* 18.09.2003	Priority date *(day/month/year)* 18.09.2002
International Patent Classification (IPC) or both national classification and IPC A61K38/47		
Applicant CANADIAN INOVATECH INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
16.04.2004	01.02.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Hars, J Telephone No. +49 89 2399-7825

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CA 03/01359

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-19 as originally filed

Claims, Numbers

1-22 received on 03.12.2004 with letter of 30.11.2004

Drawings, Sheets

1/8-8/8 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

~~These elements were available or furnished to this Authority in the following language: , which is:~~

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-22
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-22
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-22
	No:	Claims	

2. Citations and explanations

   see separate sheet

Reference is made to the following documents:

D1: EP-A-0 466 244 (UNILEVER PLC ;UNILEVER NV (NL)) 15 January 1992 (1992-01-15)
D2: EP-A-0 955 061 (MEDIPHARM CZ S R O) 10 November 1999 (1999-11-10)
D3: PATENT ABSTRACTS OF JAPAN vol. 011, no. 371 (C-462), 3 December 1987 (1987-12-03) & JP 62 145025 A (NIPPON KAYAKU CO LTD), 29 June 1987 (1987-06-29)

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

V.1 INVENTION

~~Suppression of the growth of enteric pathogens in livestock by administering an~~ antimicrobial composition comprising: a) a cell wall lysing agent (lysozyme) + b) an antimicrobial substance (dried egg powder and/or albumen) + c) a sequestering agent (EDTA, citric acid, chitosan), eventually further comprising d) a lantibiotic (nisin); also as feed additive; pathogens: Clostridium perfringens, E. coli, Salmonella typhimurium, Salmonella mbandaka.
The composition was designed to overcome restrictions on the use of classical antibiotics on livestock.

V.2 CLARITY

The applicant should delete all occurences of the relative term 'about', where this term refers to a range or to range limits.

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.

V.3 PRIOR ART

If not otherwise specified, subject matter of cited documents relates to the passages indicated in the search report.

D1
A synergistic antibacterial (e.g. Listeria decontamination) composition comprising: lysozyme, nisin and citric acid or EDTA, eventually also comprising an antimycotic (PimaricinTM); also applicable to animal feedstuffs or pharmaceutical products; also effective against other microorganisms.
The inventors observed a strong synergism when using lysozyme, nisin and citric acid, compared to the single ingredients or pairwise combinations.

The examples have at least 100 ug/mL lysozyme. A typical composition comprises:
10 mg/mL citric acid
100 ug/mL lysozyme
500 i.u./mL nisin

D2
Oral product for treatment of gastrointestinal infections of swine, comprising egg-derived antibodies to species of e.g. E. coli, Clostridium and/or Salmonella (freeze-dried egg yolks or liquid eggs).

D3
Albumen, eg in the form of liquid egg, froze whole egg, etc. is used as an antiviral composition. It can be in powdered form.

V.4 NOVELTY

Remarks under Art. 33(2) PCT

Claims 1-22 appear to be novel according to Art. 33(2) PCT.

V.5 INVENTIVE STEP

Remarks under Art. 33(3) PCT

Document D1, which is considered to represent the most relevant state of the art, discloses an antimicrobial composition from which the subject-matter of independent claims 1,21,22 differs in that the composition comprises dried egg powder and/or albumen as an antimycotic / antiviral substance instead of an antimycotic agent such as PimaricinTM in the case of D1.
The technical effect achieved is inhibition of bacterial growth at a much lower lysozyme concentration both in the case of used egg powder (which has a high amount of albumen) and / or albumen.

The problem to be solved by the present invention may therefore be regarded as how to identify an alternative antimicrobial composition.

The solution proposed in claims 1,21,22 of the present application appears to involve an inventive step (Article 33(3) PCT) for the following reasons:

The use of albumen allows to produce antimicrobial compositions with an MIC of 31.3 ppm, which is equivalent to 5.8 ug/mL lysozyme (see figure 8 and page 14; blend 3), compared to D1 which uses at least 100 ug/mL lysozyme.
A synergistic effect can thus be credibly claimed.
Lysozyme is an expensive ingredient whereas dried egg powder or albumen is not, so the finding of an antimicrobial composition comprising only 6% of lysozyme as compared to the closest prior art has to be regarded as a technical advance.

Dependent claims 2-20, in consequence, also appear to involve an inventive step.